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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,565	06/11/2007	Suresh Pareek	11336.1026USWO	8564
52835	7590	12/09/2009	EXAMINER	
HAMRE, SCHUMANN, MUELLER & LARSON, P.C.			CHAN, HENG M	
P.O. BOX 2902			ART UNIT	
MINNEAPOLIS, MN 55402-0902			PAPER NUMBER	
			1793	
			MAIL DATE	
			DELIVERY MODE	
			12/09/2009	
			PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/590,565	<b>Applicant(s)</b> PAREEK ET AL.	
	<b>Examiner</b> HENG M. CHAN	<b>Art Unit</b> 1793	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Group I, claims 1-9 in the reply filed on 9/17/2009 is acknowledged. The traversal is on the ground(s) that US 4,971,791 does not relate to film forming compositions and the reference contemplates the inclusion of sweetening agents. This is not found persuasive for reasons and explanation given in the claim rejection below.

The requirement is still deemed proper and is therefore made FINAL.

### ***Specification***

2. The specification is objected to because the term "non-water additives" recited in the 4<sup>th</sup> paragraph of page 6 should be changed to "non-soluble additives" in order to be consistent with the rest of the application.

### ***Claim Objections***

3. Claims 2-9 are objected to because a space is required between "claim" and "1."

4. Regarding claim 5, "a flavoring agent" should be changed to "the flavoring agent" so that the claim reads "A ready mix flavored composition of claim 1, wherein the flavoring agent may be volatile or non-volatile."

Appropriate corrections are required.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 4 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the instant claims recites "may be" in line 1. It is unclear whether the recited limitations are required or optional. For examination purposes, the recited limitations are considered to be optional.

7. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). Also, a conjunction is missing between the two elements: "a plasticizer" and "non-soluble additives" in claim 9. For examination purposes, "colorants, detackifiers and opacifying agents" are considered to be alternatives of non-soluble additives, and the missing conjunction is considered to be "and."

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**9. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by US 4,971,791 to Tsau et al.**

Regarding claim 1, Tsau et al. teach a drug-polymer composition, i.e. a ready mix flavored composition, comprising of an active ingredient, a copolymer (i.e. a polymer) and a flavoring agent, but without a sweetening agent and capable of masking the unpleasant taste of a solid core (abstract; from column 1, line 55 to column 2, line 2; from column 3, line 66 to column 4, line 2; column 4, lines 5-15).

The limitation “for film coating of pharmaceutical oral solid dosage form” is a recitation of the intended use of the claimed invention. The claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Tsau et al. teach that a film drying process can be used to remove a solvent from the drug-polymer composition and a film is formed in this process (from column 3, line 66 to column 4, line 2). The drug-polymer composition is thus capable of forming a film or coating a substance such as a pharmaceutical oral solid dosage form.

Regarding the sweetening agent, Tsau et al. teach using “small amounts of such sweetener(s) and/or a flavoring agent(s)” (column 4, lines 5-15). This is interpreted that sweetener(s) and flavoring agent(s) can be used together or alone. Thus, the composition that contains the copolymer and flavoring agent(s) but not the sweetener(s) anticipates the claimed composition.

**10. Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by US 2002/01320006 to Sue et al.**

Regarding claim 1, Sue et al. teach a coating, for example, one resulting from combining the third coating compartment 8 and a fourth color coat 10 of Figure 1 ([0034]), for masking or reducing the detectable presence of odor or odors, taste or tastes of pharmaceutical preparations, e.g. a pharmaceutically active tablet core 2 (abstract). All coatings can be applied using conventional film coating technology well known in the pharmaceutical industry, for example, film-coating ([0036]). That is, the coating is prepared from a composition (i.e. a ready mix flavored composition for film coating of pharmaceutical oral solid dosage form) comprising its components: a polymer and a flavoring agent ([0014]; [0088-89]). The lack of mention of a sweetening agent is understood that the coating composition does not comprise a sweetening agent.

Regarding claims 2-4, Sue et al. teach that the third coating compartment may comprise hydroxypropyl methylcellulose and ethylcellulose resin ([0014]) and the color coat may contain hydroxypropyl methylcellulose ([0089]). The resulting coat of combining the two layers may contain a combination of hydroxypropyl methylcellulose and ethylcellulose.

Regarding claim 5, Sue et al. teach using peppermint oil or other flavorant ([0089]). The flavoring agent thus may be volatile or non-volatile.

Regarding claim 6, Sue et al. teach that the composition further comprises a plasticizer ([0032]), anti-tackiness agent such as talc and other additives (i.e. non-

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soluble additives) ([0025]; [0030]; [0034-35]; Table 4) and a colorant (Example 6; [0089-90]).

Regarding claim 7, Sue et al. teach that the polymer can be hydroxypropyl cellulose ([0014]) comprising, for example, 40% w/w of the third coating compartment (Table 4; Example 4).

### ***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**14. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0132006 to Sue et al.**

Regarding claim 9, Sue et al. teach using about 0-20 % w/w of a plasticizer, and 10-70% w/w of anti-tackiness agent, i.e. non-soluble additives (Example 4; Table 4; [0032]).

Sue et al. do not expressly teach a plasticizer from about 5-25 % w/w and non-soluble additives from about 5-25% w/w based on the total weight of the composition.

However, it would have been obvious to one of ordinary skill in the art at time of invention to have arrived at the claimed weight percents in the composition disclosed by Sue et al., because a *prima facie* case of obviousness exists in the case where the claimed ranges “overlap or lie inside ranges disclosed by the prior art”. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). See MPEP 2144.05[R-5].

**15. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sue et al. as applied to claim 1 above, in view of US 5,098,715 to McCabe et al.**

Regarding claim 8, Sue et al. do not expressly teach the amount of flavoring agent.



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The absence of such a specific teaching would clearly suggest to one of ordinary skill in the art at time of invention that any conventionally known amount can be used. In view of this, the skilled artisan would have used any conventionally known amount. For example, McCabe et al., who also relate to flavored film-coated tablet, teach using 2.0% w/w based on a coating dispersion in Example 2 (also column 4, lines 41-63).

It would have been obvious to one of ordinary skill in the art at time of invention to have obtained the claimed amount of flavoring agent in the composition provided by Sue et al., motivated by the fact that McCabe et al. teach that the preferred flavoring amount is readily determined by balancing the goal of adding an amount sufficient to mask the core tablet taste and provide a distinct, characteristic and pleasing taste, and the goal of keeping the tablet from being too much like a candy or mint product. The desired strength of the flavoring may vary depending on the type of tablet and the intended recipients and the identity of the flavoring (column 5, lines 11-19). The skilled artisan would have therefore optimized the amount of flavoring agent in the composition provided by Sue et al. in order to achieve the desired strength of flavoring.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HENG M. CHAN whose telephone number is (571)270-5859. The examiner can normally be reached on Monday to Friday, 8:00 am EST to 5:30 pm EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry Lorengo can be reached on (571)272-1233. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Examiner, Art Unit 1793

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